JAN 1 3 2012 K110730

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter: BIOMET *3i*
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Establishment Reg. Number: 1038806

Contact: Mayank Choudhary
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Date Prepared: December 15, 2011

Trade/Proprietary Name: ***Encode Patient Specific Abutment for Straumann Bone Level Connection***

Common/Usual Name: Dental Implant Abutment

Classification Name/ FDA Reviewing Branch: Abutment, implant, dental, endosseous/ Dental Panel

Device Classification/Code: Class II - 21 CFR §872.3630 / NHA

Predicate Device Manufacturer: K110565 – Encode Patient Specific Abutment for Nobel Replace Connection

Purpose of the *SPECIAL* 510(k) notice: The reason for this *Special* 510k submission is to request clearance for a modification to a device that has been cleared under the 510(k) process referred to herein as ***Encode Patient Specific Abutment for Straumann Bone Level Connection.*** Dental Implant Abutment are referenced under 21 CFR §872.3630 and are considered Class II devices.

Device Description: BIOMET *3i* Encode Patient Specific Abutment for Straumann Bone Level Connection can be compared to current Encode Patient Specific Abutment for Nobel Replace Connection. The change to this device is only to the connection that is intended to interface which is identical to the interface found on the STRAUMANN bone level

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Implant. This feature does not modify the intended functionality of the implant/abutment system. This device is also intended for dental laboratories to provide limited design input to match the anatomical requirements of the patient.

Indications for Use: BIOMET *3i* Dental Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw or cement retained to the abutment. For compatibility of Bellatek™ Patient Specific Abutments, please refer to the Table below.

Compatibility Chart for Patient Specific Abutments

Bellatek™ Patient Specific Abutment (EDA and EDAX)		
Manufacturer	**Implant**	**Platform (mm)**
Biomet *3i*	**Biomet3i Certain Osseotite, Nanotite**	**3.4**
		4.1
		5
		6
	Biomet3i Ex-Hex Osseotite, Nanotite	**3.4**
		4.1
		5
		6
Nobel Biocare	**Internal Connection Nobel Replace Implant**	**3.5**
		4.3
		5
		6
Straumann	**Straumann Bone Level Implant**	**3.3**
		4.1
		4.8

Technological Characteristics : The predicates and ***Encode Patient Specific Abutment for Straumann Bone Level Connection*** have a number of very similar and equivalent design / technological characteristics, as follows:

Element of Comparison	Proposed BIOMET *3i* Patient Specific Abutment for Straumann Connection	Predicate Encode Patient Specific Abutments for Nobel Replace

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Indications	The *3i* Patient-Specific Dental Abutment is intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.	The *3i* Patient-Specific Dental Abutment is intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.
Mating Connection	Anti-rotational, internal engagement feature compatible with Straumann Bone Level	Nobel Replace anti-rotational, internal engagement feature compatible with Nobel Replace
Statistical tolerance analysis	Yes	Yes
Compatible Platforms	3.3mm ,4.1mm, 4.8mm	3.5mm , 4.3mm, 5.0mm, 6.0mm
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Biocompatible	Yes	Yes
Screw Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI

Performance Data: BIOMET *3i* has conducted Design Verification Testing according to ISO 14801:2007 *"Dentistry – Dynamic Fatigue Test for Endosseous Dental Implants"* on the ***Encode Patient Specific Abutment for Straumann Bone Level Connection*** under this submission. All testing conducted met the acceptance criteria and evaluated the worst case scenario including 30° pre-angled abutments as compared to predicate BIOMET *3i* designs commercially in the marketplace. Performance testing data indicates that the subject device demonstrate substantial equivalence to the predicate device. Bench Testing conducted outlined in the FDA Guidance referenced above demonstrates that the proposed device meets the mechanical properties recommendations by FDA.

Clinical Data: N/A

Performance Standards: The following FDA Guidance Document for this type of product was utilized in this submission: ***"Guidance for Industry and FDA Staff: - Special Controls Class II - Root Form Endosseous Dental Abutment/ Implant".*** Also, Testing was conducted following ISO standard **14801:2007** Dentistry -- Implants – ***"Dynamic fatigue test for endosseous dental implants".*** The test articles met all predetermined acceptance criteria.

Substantial Equivalence: The ***Encode Patient Specific Abutment for Straumann Bone Level Connection*** included in this submission have the same intended use, indications for use, technological characteristics, and principles of operation as previously cleared Encode Patient Specific abutment for Nobel replace connection per the 510(k) number referenced in the Predicate Devices section above.

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Refer to the following substantial equivalence data table:

Element of Comparison	Proposed BIOMET *3i* Patient Specific Abutment for Straumann Connection	Predicate Encode Patient Specific Abutments for Nobel Replace
Indications	The *3i* Patient-Specific Dental Abutment is intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.	The *3i* Patient-Specific Dental Abutment is intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.
Mating Connection	Anti-rotational, internal engagement feature compatible with Straumann Bone Level	Nobel Replace anti-rotational, internal engagement feature compatible with Nobel Replace
Statistical tolerance analysis	Yes	Yes
Compatible Platforms	3.3mm ,4.1mm, 4.8mm	3.5mm , 4.3mm, 5.0mm, 6.0mm
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Biocompatible	Yes	Yes
Screw Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI

Conclusion:

Encode Patient Specific Abutment for Straumann Bone Level Connection and predicate designs have the same intended use, indications for use, similar technological characteristics, and principles of operation. The major technological difference between the *Encode Patient Specific Abutment for Straumann Bone Level Connection* and its predicates is:

The change is only to the connection that is intended to interface which is identical to the interface found on the Straumann bone level Implant.

The information demonstrates that the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Mayank Choudhary
Regulatory Affairs Specialist
BIOMET 3i
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

JAN 13 2012

Re: K112730
Trade/Device Name: Encode Patient Specific Abutment for Straumann Bone Level Connection
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 15, 2011
Received: January 5, 2012

Dear Mr. Choudhary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112730

Device Name: ***Encode Patient Specific Abutment for Straumann Bone Level Connection***

Indications for Use: BIOMET *3i* Dental Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw or cement retained to the abutment. For compatibility of Bellatek™ Patient Specific Abutments, please refer to the Table below.

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		5
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		4.1
		4.8

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Prescription Use ___X___ **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **AND/OR** **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112730